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H- 9 USE OF HUMAN SUBJECTS (1978 Aug)

- (a) The following definitions are used in this clause:
- (1) At risk means that the human subject may be exposed to the possibility of harm physical, biological, psychological, sociological, or other as a consequence of an act or omission that goes beyond the application of those established and accepted methods or procedures which are in his best interests, or that incresses ordinary risks of daily life, including the recognized risks inherent in his chosen occupation or field of service.
- (2) Human Subject means any human being who, knowingly or unkowingly, is subjected to an act or omission, whether at risk or not, the object of which is to contribute to knowledge to be gained as a part of work to be performed under the scope of this contract.
- (b) The Contractor, before undertaking to perform any study involving human subjects, whether at risk or not, shall insure that the following minimum conditions are complied with:
- (1) The proposed study has been reviewed and approved by a committee meeting the requirements set forth in Chapter 46 of Title 45 of the Code of —Federal Regulations.
 - (2) The number of human subjects used will be kept to the minimum number that will reasonably achieve the required results.
 - (3) The study must be such as to contribute significantly to scientific knowledge and have reasonable prospects of yielding important results essential to an Army research program.
 - (4) The study will be conducted only by persons possessing the requisite scientific qualifications. The highest degree of skill and care will be required during all stages of study of persons who conduct or assist in the study.
 - (5) The human subject will be informed that at any time during the course of his participation he has the right to revoke his consent and withdraw from participation without prejudice to himself.
 - (6) Participation by subjects will be immediately terminated if it subsequently appears that the risk to the subjects is significantly greater than anticipated at the time review and approval was granted.
 - (7) There shall be no greater intrusion into the privacy of the human subject than is absolutely necessary for the conduct of the study involved. Except for the submission of reports and other data required by this contract, any information obtained about human subjects as a result of their participation shall be held as confidential as the law allows.
 - (8) The study will be conducted so as to avoid all unnecessary physical or mental suffering or injury.

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- (9) No study will be conducted if there is any inherent reason to believe that death or disabling injury is likely to occur. Sufficient animal or laboratory experiments, or other evaluations, must have been completed to give assurance of acceptable risks prior to the use of human subjects.
- (10) The degree of risk to be taken will never exceed that which is justified by the benefit to the subject and/or the humanitarian importance of the knowledge to be gained.
- (11) A physician will be responsible for the medical care of subjects. Even if not the project leader, the physician will have authority to terminate the study at any time that he believes death, injury or harm is likely to result.
- (12) Proper preparations will be made, and adequate facilities provided, to protect the subject against all foreseeable possibilities of injury, disability, or death. This includes but is not limited to hospitalization and medical treatmen as may be required. In addition, all apparatus and instruments necessary to deal with likely emergency situations will be available.
- (13) Human subjects will have no physical or mental conditions which will make participation more hazardous for them than it would be for normal healthy persons, unless such condition is a necessary prerequisite for the particular study involved. In any such case, the use of human subjects with such pre-existing conditions must have been specifically described and justified in the scope of the work to be performed under this contract.
- (14) The scientifically qualified person conducting the study, and each member of his research team, will be prepared to terminate the subject's participation at any stage if he has reason to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that continuation is likely to result in injury, disability, or death to the human subject.
- (c) The Contractor, before permitting any person to participate as a human subject, whether at risk or not, shall insure that the following minimum conditions are complied with:
- (1) Legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this clause.
- (2) All consent must be voluntary. It must be the knowing consent of the individual or his legally authorized representative, so situated as to be able to exercise free power of choice without there having been any use of force, fraud, deceit, duress, constraint, coercion, or lawful or improper inducement. The elements of information necessary to such consent include:
- (i) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental.
- (ii) A description of any attendant disconforts or risks reasonably to be anticipated.

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- (111) A description of any benefits reasonably to be anticipated.
- (iv) A disclosure of any appropriate alternative procedures that might be advantageous to the subject.
 - (v) An offer to answer any questions concerning the procedure.
- (vi) An instruction that the subject is free to revoke his consent and to discontinue participation at any time without prejudice to himself.
- (d) Exculpatory language through which the subject is made to waive, or appear to waive, any of his legal rights, including any release from liability for negligence, is prohibited.
- (e) Prior consent by a subject or his legally authorized representative shall be obtained in all cases. Such consent shall be in writing whenever it is reasonably possible to do so. The consent form may be read to the subject or his legally authorized representative, but in any event he or his legally authorized representative must be given adequate opportunity to read it and to ask questions they might have. This consent form should then be signed by the subject or his legally authorized representative and by a witness not directly involved in the study. Oral consent may be used only when it has been specifically described and justified in the scope of the work to be performed under this contract or approved in writing by the contracting officer. When so authorized and used, oral consent is subject to all the same standards as apply to written consent, except that the signature of the subject or his legally authorized representative is not required.
- (f) Prior to conduct of the study, the contractor shall submit for approval to the contracting officer a detailed description of the means by which informed consent will be obtained, to include any forms to be used. Upon completion of the study, the contractor will submit to the contracting officer detailed report demonstrating compliance with paragraph (c), to include copies of the written consent if such was obtained.
- (g) The Contractor shall not undertake to conduct either the clinical pharmacology or clinical trails of an investigational drug unless this contract contains the clause entitled "Clinical Study of Investigational Drugs."
 - (h) Prisoners of war will not be used under any circumstances.
- F. Add the following as paragraph H.10 of the contract:
 - H.10 All persons participating as human subjects, as defined by paragraph
 H.9(a)(2) hereof, shall be known to possess the abilities and qualities
 which will be observed and analyzed during the conduct of this contract.

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G. Military security requirements in the performance of contract MDA908-81-C-0004 as modified shall be maintained in accordance with the revised DD Form 254 attached hereto. The highest classification involved in the performance of this contract as modified is TOP SECRET.

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Approved For Release 2001/04/02 : CIA-RDP96-00788R001500110012-2

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DEPARTMENT OF DEFENSE CONTRACT SECURITY CLASSIFICATION SPECIFICAT	ION	AP	PLY TO	LL SECURIT	TY ASI	DOD INDUSTRIA PECTS OF THIS ARANCE REQUI	Tor	Secre	_	
2. THIS SPECIFICATION IS FOR: On the contract number or other identification number (Prime contracts must be shown for all subcontracts)			DATE TO BE COMPLETED (Estimated)		5. THIS SPECIFICATION IS: (See "NOTE" below. If item b or c is "X'd", elso enter date for item s)					
X PRIME CONTRACT MDA908-81-C-00	MDA900-01-C-0004			APRO5	ORIGINAL (Complete date in all cases)				R06	
b. SUBCONTRACT(Use item b. FIRST TIER SUBCONTI	b. SUBCONTRACT(Use item b. FIRST TIER SUBCONTRACT NO. 15 for subcontracting beyond second tier)		b.		Х	b. REVISED (supersedes all previous apecilications	REVISION	BLAUC	UG21	
C. REQUEST FOR BID. REQUEST FOR PROPOSAL OR REQ FOR QUOTATION	EQUEST FOR PROPOSAL			DATE		C. FINAL	<u></u>	DATE	,	
6. Is this a follow-on contract? [X] Yes No. If YES, complete the following: a. MDA903-81-C-0292 b. c. Accountability for classified material on preceding contract PRECEDING CONTRACT NUMBER DATE COMPLETED [XXis										
c. Are there additional security requirements established in accordance with paragraph 1-114 or 1-115, ISR? Yes No. If YES, identify the pertinent contractual documents in Item 15. d. Are any elements of this contract outside the inspection responsibility of the cognizant security office? Yes No. If YES, explain in Item 15 and identify specific areas or elements.										
11. ACCESS REQUIREMENTS	YE	NC NC	ACCESS REQUIREMENTS (Continued)						V = C	
a. Access to Classified Information Only at other		1	J. Access to SENSITIVE COMPARTMENTED INFORMATION.						YES	МО
contractor/Government activities.					pecial Access Program information					\Box
 Receipt of classified documents or other material for reference only (no generation). 	X		(Specify in Item 15). 1. Access to U. S. classified information outside the U. S.					S,		X
 Receipt and generation of classified documents or other material. 	X		and '	Panama Canal Zone, Puerto Rico, U. S. Possessions and Trust Territories. m. Defense Documentation Center or Defense information						X
d. Fabrication/Modification/Storage of classified hardware.		Х	Analysis Center Services m							
e. Graphic arts services only.		X	n. Classified ADP processing will be involved.						X	
f. Access to IPO information. g. Access to RESTRICTED DATA.		13	o. REMARKS:							
h. Access to classified COMSEC information.	+	1 X		DOD DIR 5200.17 DOD DIR 5200.1R						- 1
i. Cryptographic Access Authorization required.	+	$\frac{1}{x}$								- 1
12. Refer all questions pertaining to contract security classific EMERGENCY, direct with written record of inquiry and resp	ation onse i	specific	ation to t	ne official name contractor i	med be	low (NORMALL)	, thru ACO (item 16e);	• • • • • • • • • • • • • • • • • • • •	
a. The classification guidance contained in this specification a	nd att	ochment	s referenc	ed herein is	comple	te and adequate.	·····			\dashv
Deputy Directorate for Scientific a Technical Intelligence	C. Activity name, address, Zip Code, telephone number and office symbol Defense Intelligence Agency ATTN: DT-1A Washington, D.C. 20301 SG1J									
Defense Intelligence Agency NOTE: Original Specification (Item 5a) is authority for contracted authority for contracted		mark of								
authority for contractors to remark the regraded classifie of the Industrial Security Manual.	d info	mation.	Such ac	tions by contr	actors	shall be taken ii	ncations (]te accordance	ms 55 and with the p	c) are rovisi	ons

3a. Information pertaining to classified contracts or projects, even though such information is considered unclassified, shall not be released for public dissemination except as provided by the Industrial Security Manual (paragraph 50 and Appendix IX).									
. Proposed public releases shall be submitted for approval prior to release [] Direct [] Through (Specify):									
Public Release of SCI is not Authorized.									
to the Directorate For Freedom of Information and Security Review, Office of the Assistant Secretary of Defense (Public Affairs) * for review in accordance with paragraph 50 of the Industrial Security Manual. * In the case of non-DoD User Agencies, see footnote, paragraph 50, Industrial Security Manual.									
4. Security Classification Specifications for this solicitation/contract are identified below ("X" applicable box(es) and supply attachments as required), Any narrative or classification guide(s) furnished shall be annotated or have information appended to clearly and precisely identify each element of information which requires a classification. When a classification guide is utilized, that portion of the guide(s) pertaining to the specific contractual effort may be extracted and furnished the contractor. When a total guide(s) is utilized, each individual portion of the guide(s) which pertains to the contractual effort shall be clearly identified in Item 14b. The following information must be provided for each item of classified information identified in an extract or guide: (I) Category of classification. (II) Date or event for declassification or review for declassification, and (III) The date or event for downgrading (II applicable). The official named in Item 12b, is responsible for furnishing the contractor copies of all guides and changes thereto that are made a part of this									
apecification. Classified information may be attached or furnished under separate cover.									
a. A completed narrative is (1) attached, or (2) transmitted under separate cover and made a part of this specification. b. The following classification guide(s) is made a part of this specification and is (1) attached, or (2) transmitted under separate cover. (List guides under Item 15 or in an attachment by title, reference number and date).									
c. Service-type contract/subcontract. (Specify instructions in accordance with ISR/ISM, as appropriate.).									
d. "X" only if this is a final specification and Item 6 is a "NO" answer. In response to the contractor's request dated,									
retention of the identified classified material is authorized for a period of									
15. Remarks (Whenever possible, Illustrate proper classification, declassification, and II applicable, downgrading instructions). a. This contract requires access to SCI. The Defense Intelligence Agency has exclusive security responsibility for such information released to the contractor or developed under this contract. DIAM 50-5 provides the necessary guidenace for physical, personnel and information security measures and is a part of the security specifications for this contract. DCASR is relieved of responsibility for all SCI material or information released to the contractor under this contract.									
b. Foreign national employees of the contractor or subcontractor(s) are not authorized access to classified information resulting from or use in the performance of this contract.									
c. The Contractor shall notify the COTR in writing no later than five (5) days after receipt of the contract of the following information regarding the individuals assigned to work on this contract.									
(1) Name(2) Date and Place of Birth(3) Social Security Number									
(SEE CONTINUATION SHEET)									
16a. Contract Security Classification Specifications for Subcontracts issuing from this contract will be approved by the Office named in Item 16e below, or by the prime contractor, as authorized. This Contract Security Classification Specification and attachments referenced herein are approved by the User Agency Contracting Officer or his Representative named in Item 16b below.									
REQUIRED DISTRIBUTION:									
□ Prime Contractor (Item 7a) SG1J SG1J SG1J SG1J									
Cognizant Security Office (Item 7c) Asst. Director for Security Services									
Administrative Contracting Office (Item 16e) SG1J									
X Quality Assurance Representative Subcontractor (Item 8a)									
(X) Cognizant Security Office (Item 8c)									
Program/Project Manager (Item 12b) Defense Intelligence Agency									
U. S. Activity Responsible for Overseas Security Administration The Pentagon, RSS Washington, D.C. 20301									
ADDITIONAL DISTRIBUTION: e. Name, address and Zip Code of Administrative Contracting Office									
DCASMA San Francisco									
Approved For Release 2001/04/02 : \$ Approved For Release 2001/04/02 : \$ Approved For Release 2001/04/02									
San Brutto CA 940000 Too 12-2									

DD Form 254 (Continued)

- (4) Certification of clearance investigation and clearance, date clearance granted, and name of agency granting clearance.
- c. Final classification of the information generated under this Contract is the responsibility of DIA (DT-1A). Information generated under this Contract is subject to the guidelines contained in DoD Regulation 5200.1R, dated 2 November 1978, which implements EO 12065 which became effective 1 December 1978. Technical reports classified as high as TOP SECRET SI/SAO will be provided the Contractor by DIA and other DoD activities, and other DoD contractors for use in connection with this Contract. These reports may be retained for the duration of this Contract unless no longer needed. Upon termination of this Contract, the reports shall be returned to the sender (if required) or destroyed in accordance with current security regulations. If these documents are to be retained beyond the ending date of this Contract, written justification must be forwarded to and authorization given by the Contracting Officer.
- e. All copies of final documents generated by the Contractor under this Contract will be transmitted to DIA (DT-1A) for dissemination to the Grill Flame Committee. No other distribution is authorized.
 - f. Use of the ARFCOS system is required.